

***Detailed Action***

Status of claims. Claims 1-20 and 22-43 are pending. Claims 1, 6, 8, 10, 15, 16, 17, 20, 26, 27, 28, 42 and 43 have been amended by applicants' amendment filed on 12-30-2009. Claims 9, 18 and 29 were previously withdrawn from consideration as being directed to non-elected species pursuant to 37 CFR 1.14(b), there being no allowable generic or linking claim.

The examiner contacted Applicant's representative on March 23, 2010 to discuss a proposed amendment to independent claims 1, 10, 20, 42 and 43 of Applicants' amendment filed on 12-30-2009 to overcome claims rejection under 35 U.S.C. 103(a), the amendment comprising: insertion of the limitation of SEQ ID NO:2 in subpart (i) of claims 1 and 10; subparts (i)(a) of claim 20; subpart (a) i) of claim 42 and subpart (i) i) of claim 43, cancellation of claims 6, 15 and 26 and amendment of both, claim 7 to correct its dependency and withdrawn claims 9, 18 and 29 to remove the parenthesis and eliminate the redundancy in order to set forth the claims in condition for allowance.

Authorization for the Examiner's amendment was given in a telephone interview with Mark Graham, on March 24, 2010. With respect to the proposed claims, an Examiner's amendment to the records appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

Claims 1-5, 7, 8, 10-14, 16, 17, 19, 20, 22-24, 27, 28 and 30-43 are allowable. Claims 9, 18 and 29 are drawn to species of generic genus claims 8, 16 and 27, respectively. Because the genus claim is allowable as originally claimed, other species are rejoined for search and

examination. Accordingly, claims 9, 18 and 29 have been examined and meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Therefore, claims 1-5, 7-14, 16-20, 22-25 and 27-43 are allowable.

***In the claims,***

- 1) Claims 6, 15 and 26 have been cancelled.
- 2) Correct claims 1, 7, 9, 10, 18, 20, 29, 42 and 43 as follows:

Page 2, line 3 of **claim 1**, add the phrase --of SEQ ID NO: 2-- in front of "and";

Page 2, line 1 of **claim 7**, the number "6" is replaced by --1--;

Page 3, line 3 of **claim 9**, the phrase "(SEQ ID NO: 6)" is replaced by -- SEQ ID NO: 6--, and lines 4 to 7 of claim 9 are deleted;

Page 3, line 3 of **claim 10**, add the phrase --of SEQ ID NO: 2-- in front of "and";

Page 4, line 3 of **claim 18**, the phrase "(SEQ ID NO: 6)" is replaced by -- SEQ ID NO: 6--, and at page 5, lines 4 to 7 of claim 18 are deleted;

Page 5, line 5 of **claim 20**, add the phrase --of SEQ ID NO: 2-- in front of "and";

Page 6, line 3 of **claim 29**, the phrase "(SEQ ID NO: 6)" is replaced by -- SEQ ID NO: 6--, and lines 4 to 7 of claim 29 are deleted;

Page 8, line 4 of **claim 42**, add the phrase --of SEQ ID NO: 2-- in front of "and";

Page 8, line 4 of **claim 43**, add the phrase --of SEQ ID NO: 2-- in front of ", a promoter".

***Reasons for allowance***

The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or suggest of:

An expression vector, a prokaryotic host cell containing said expression vector and a process for production of a polypeptide of interest comprising said host cell, the vector comprising a polynucleotide which encodes a heterologous fusion protein containing: (i) a single signal sequence polypeptide consisting of the signal sequence of the gac gene of *Pseudomonas diminuta* of SEQ ID NO: 2 and (ii) a polypeptide of interest other than gac gene of *Pseudomonas diminuta*, wherein said signal sequence and said polypeptide of interest are linked so that upon expression of the polynucleotide as a fusion protein in a suitable host cell, the signal sequence is cleaved off the fusion protein and the polypeptide of interest is released into the periplasm of the host cell.

***Rejections/Objections withdrawn in response to Applicants' arguments or amendments:***

***Claim Rejections - 35 USC § 103(a)***

In view of Applicants' amendment of claims 1, 10, 20, 42 and 43, rejection of claims 1-3, 6-8, 10-12, 15-17, 19, 20, 22-23, 26-28 and 30-43 under 35 U.S.C. 103(a) as being unpatentable over Peleg et al., (WO 03/004599 A2, Date of Publication 16-Jan-2003) in view of Matsuda et al. (J. of Bacteriology, 1985, p. 1222-1228), Ishii et al., (Journal of Fermentation and Bioengineering, 1994, pp. 591-597) or Kim et al., (Biotechnology Letters, 2001, pp. 1067-1071) has been withdrawn.

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In view of Applicants' amendment of claims 1, 10, 20, 42 and 43, rejection of claims 4, 5, 13, 14, 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over Peleg et al., (WO 03/004599 A2, Date of Publication 16-Jan-2003) in view of Matsuda et al. (J. of Bacteriology, 1985, p. 1222-1228), Ishii et al., (Journal of Fermentation and Bioengineering, 1994, pp. 591-597) or Kim et al., (Biotechnology Letters, 2001, pp. 1067-1071) as applied to claims 1-3, 6-8,

10-12, 15-17, 19, 22-23, 26-28, 30-43 above and further in view of Kwon et al., WO 01/057217, Date of publication 9 August 2001) has been withdrawn.

***Claim Rejections - 35 USC § 112- Second Paragraph***

In view of Applicants' amendment of claims 16, 27, 42 and 43 to specify that the first and second nucleotides are operatively linked from the same promoter, rejection of claims 16, 27, 42 and 43 under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language has been withdrawn.

In view of Applicants' amendment of claims 1, 10, 20, 42 and 43 to replace the phrase "such as" with "so that," rejection of claims 1-8, 10-17, 19, 20, 22-28 and 30-43 under 35 U.S.C. 112, second paragraph, has been withdrawn.

***Claim objection***

In view of Applicants' amendment of claims 6, 8, 15, 17, 26 and 28, objection to claims 6, 8, 15, 17, 26 and 28 because of the recitation of both, the SEQ No identifier in parenthesis and the description of the nucleotide sequence has been withdrawn.

***Conclusion***

Claims 1-5, 7-14, 16-20, 22-25 and 27-43 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Voitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maria Leavitt/

Maria Leavitt  
Primary Examiner, Art Unit 1633

